

Regulatory Update: 7CFR330 Amendment Implications for Biocontrol

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7CFR 330 Amendment

- ▶ **Draft proposed rule is currently in USDA Departmental Review**
- ▶ **Draft Environmental Impact Statement completed**

330.200: Scope and General Restrictions

- ▶ **Plant pests, biological control organisms, and associated articles require a permit to be:**
 - **Imported**
 - **Moved interstate**
 - **Transited**
 - **Released into the environment**
 - **Possessed**

330.200 (cont.)

▶ Exceptions:

- Plant pests, biological control organisms, and associated articles regulated in 7CFR301**
- Plant pests, biological control organisms, and associated articles exempted from regulation in part 330**

330.200 (continued)

- ▶ **Plant pests and Biocontrol Organisms:**
 - **APHIS regulates according to the “direct and indirect effect” criteria**

330.200 (continued)

Biological control organisms:

- **Invertebrate competitors and predators of invertebrate plant pests**
- **Invertebrate herbivores of noxious weeds**
- **Microbial pathogens of invertebrate plant pests and noxious weeds**
- **Microbial parasites of plant pathogens**
- **Other organisms designated by APHIS**

330.200 (continued)

- ▶ **Biological control organisms currently not regulated by APHIS include:**
 - **Bacteriophages**
 - **Mycoviruses**
 - **Viruses of insect plant pests**
 - **Biological control organisms regulated by EPA**

330.201: Permit requirements

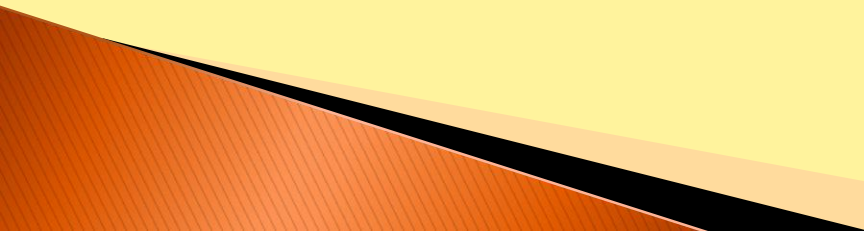
- ▶ **Establishes requirements for:**
 - **Import permits**
 - **Interstate movement permits**
 - **Continued curation permits**

- ▶ **Transit permits:**
 - **Requirements will remain in 7 CFR part 352, but will include biological control organisms and associated articles**

330.202 Biological control organisms

- ▶ **Establishes three risk-based categories for biological control organisms:**
 - **Bio-C**
 - **Bio-B**
 - **Bio-A**

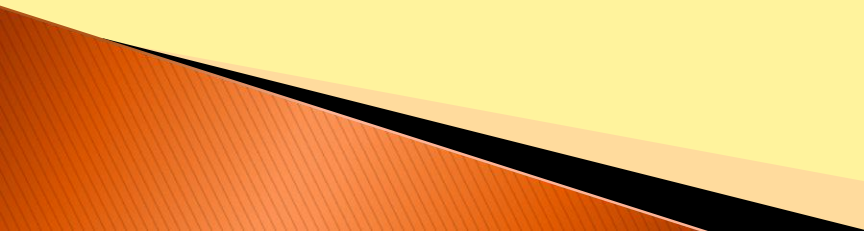
Bio-C organisms

- ▶ **Highest risk category**
 - ▶ **Organisms not yet assessed by APHIS for their potential risk to plants and other aspects of the environment**
 - ▶ **Permits are required for importation and interstate movement**
 - ▶ **No environmental release authorized**
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Bio-B organisms

- ▶ **Assessed by APHIS for the potential risk to plant health and the environment associated with their proposed release**
- ▶ **The assessment must conclude that no adverse impacts due to non-target effects are anticipated as a result of any environmental release of the organism (initial or subsequent)**

Bio-B organisms (cont.)

- ▶ **Permits required for importation and interstate movement**
 - ▶ **Can be released into an assessed area of the United States**
 - ▶ **Will be listed on-line**
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Additions to Bio-B category

- ▶ **Notice-based approach:**
 - **Petition or permit application**
 - **Classical biocontrol organism petitions typically are reviewed by an advisory group**
 - **If criteria for 1st time release are fulfilled, an environmental assessment will be developed and published for public comment**
 - **A “finding of no significant impact” must be found prior to authorizing 1st time release**
- ▶ **Addition to the list is distinct process from review of the permit application**

Bio-A organisms

- ▶ **Organisms that are established throughout their ecological range within the continental United States, and for which we have determined that subsequent environmental releases will not result in adverse impacts**
- ▶ **Will be listed on-line**

Bio-A organisms (cont.)

▶ Importation:

- Permits required for most importation**
- Implement the certification protocol in RSPM No. 26**

▶ Interstate movement:

- No permit required in the continental United States**
- Permit required for movement to or from Hawaii, etc.**

Bio-A organisms (cont.)

▶ Environmental release:

- No permit required for release in the continental United States**
- Permit required for release within Hawaii and the Territories**

Microbial Biocontrol Organisms

- ▶ **Organisms registered by the Environmental Protection Agency will be added to the Bio-A list.**

Removal from Bio-B or Bio-A categories

- ▶ **Notice-based approach**
- ▶ **Requires science-based evidence**
- ▶ **Evidence must show that organism is having adverse impacts that were not anticipated (i.e. non-target impacts)**

EPA FIFRA – pesticide definition

- ▶ **(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest,**
- ▶ **(2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and**
- (3) any nitrogen stabilizer.**

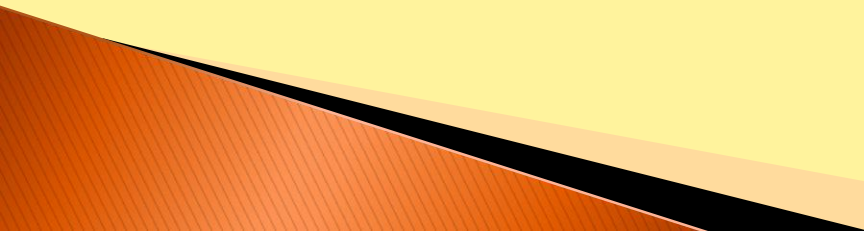
EPA FIFRA pest definition

- ▶ **Pests are living organisms that occur where they are not wanted or that cause damage to crops or humans or other animals. Examples include:**
- ▶ **insects, mice and other animals, unwanted plants (weeds), fungi, microorganisms such as bacteria and viruses, and prions.**

Plant Protection Act – Plant Pest

Any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product including:

Protozoans, nonhuman animals, parasitic plants, bacterium, fungus, virus or viroid, infectious agents or other pathogens, and any article similar to or allied with any of the articles specified in the preceding subparagraphs.



Regulatory Authority - Biocontrol

- ▶ **Biocontrol organism: Any enemy, antagonist, or competitor used to control a plant pest or noxious weed.**
- ▶ **EPA regulates microbial biocontrol organisms based on “intent” – thus if there are no pesticidal claims – EPA doesn’t regulate.**
- ▶ **APHIS regulations are based on plant pest potential. APHIS has broad authority to regulate plant pests.**

EPA vs APHIS Regulatory Policy

- ▶ **Microbial biocontrol agents isolated in USA will NOT require an APHIS permit for interstate movement or release in the environment (EPA will continue its current oversight of these microbes).**
- ▶ **Viruses of fungi, insects, and bacteria are EXEMPT from all APHIS oversight (EPA will continue its current oversight of these microbes).**
- ▶ **APHIS oversight will focus on Microbial biocontrol agents originally isolated in foreign countries**

Experimental Use Permits

An experimental use permit is a permit under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136c) that authorizes the testing of new pesticides or uses thereof in experimental field studies on 10 acres (40,000 m²) or more of land or 1-acre (4,000 m²) or more of water. Such tests provide data to support registration of pesticides.

EPA vs. APHIS regulatory policy

If the release is regulated by EPA under EUP then PPQ typically will not require a permit

Typically, APHIS regulates release of non-exempt organisms under 7CFR330 on acreages of 10 acres or less (land) or 1 acre or less (water).



EPA vs. APHIS regulatory policy

- ▶ **APHIS will require a 526 permit to import these products (by EPA strain number) to help facilitate their movement thru the port of entry.**
- ▶ **Movement can be by any applicant not just registrant.**
- ▶ **Subsequent movements will NOT require an APHIS permit if environmental release of the microbe is authorized by EPA.**

EPA vs. APHIS regulatory policy

- ▶ **Field release involves EPA/USDA consultation.**
- ▶ **During this consultation, plant pest status of the organism is determined.**

Environmental review for field releases of foreign organisms

- ▶ **APHIS acknowledges that small scale release of microbial biocontrol agents has occurred without Federal oversight for decades without identifiable adverse environmental impacts**
- ▶ **APHIS believes most, but not all, field testing of potential microbial biocontrol agents can proceed without an environmental assessment (EA)**

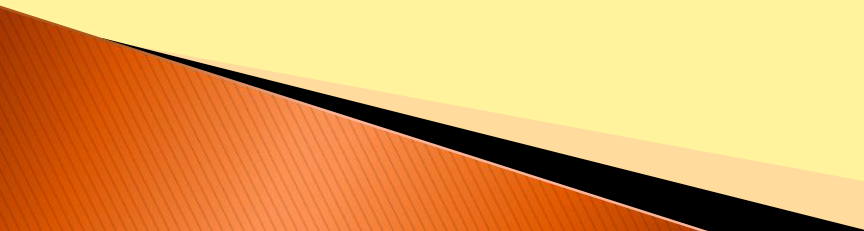
National Environmental Policy Act (NEPA) Requirements

If a foreign microbe is exotic to United States, and has not been reviewed by a competent authority, development of an Environmental Assessment may be required.

Foreign isolate registered by a foreign competent authority

- ▶ **APHIS will NOT accept a decision in foreign country without its own internal review**
- ▶ **APHIS believes that for some approved products there is sufficient scientific data that would greatly aid APHIS' hazard identification process**
- ▶ **Applicants could provide data obtained from the competent authority, but additional data might be required.**

Considerations – NEPA evaluation

- ▶ **Foreign isolate is similar or identical to the microbe in US**
 - ▶ **Foreign isolate is similar to EPA registered microbial pesticide**
 - ▶ **Foreign isolate is registered by a competent authority**
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Environmental Assessment Worksheet

- ▶ **An environmental assessment worksheet will be used to evaluate if adverse effects on threatened and endangered species (TES), their habitats, and significant impact on the environment are likely to occur as a result of the proposed release.**
- ▶ **Establishment of a Technical Advisory Group??**

Field release of attenuated plant pests: potential microbial biocontrol organism

If a wild type of pathogen release qualifies for NEPA Categorical Exclusion (CAT-EX) at a specific site, the release of an attenuated/avirulent strain at the same site would be also CAT-EX

Thank You

Questions

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